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INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

(Use as many sheets as necessary)

APPLICATION NO.:
10/674,268

FILING DATE:
September 29, 2003

FIRST NAMED INVENTOR:
Michael Fantuzzi
1652

EXAMINER NAME:
KOSSON, Rosanne
33503/US

| U.S. PATENT DOCUMENTS  |             |  |                             |                                       |  |
|--|-------------|--|-----------------------------|---------------------------------------|--|
| EXAMINER<br>INITIALS*  | Cite<br>No. | PATENT NUMBER Number - Kind Code <sup>2</sup> (If known) | ISSUE<br>DATE<br>MM-DD-YYYY | Name of Patentee of Cited<br>Document | Pages, Columns, Lines,<br>Where Relevant Passages<br>or Relevant Figures Appea   |
| ة -<br>الكفيد فلاد الروايد أن الجياب   | 1.          | 4,343,816  | 08/1982                     | Cavazza                               |  |
|  | 2.          | 4,687,782  | 08/1987                     | Brantman                              |  |
| ر ا<br>المار وراء المار الم  | 3.          | 5,030,458  | 07/1991                     | Shug et al.                           |  |
|  | 4.          | 5,240,961  | 08/1993                     | Shug                                  |  |
| المراجع المسترة المائش مما   | 5.          | 5,362,753  | 11/2994                     | Blum et al.                           |  |
| \$ 10 E. K. B. B.  | 6.          | 5,391,550  | 02/1995                     | Carniglia et al.                      |  |
|  | 7.          | 5,504,072  | 04/1996                     | Schmidl et al.                        |  |
| Like of the last of the  | 8.          | 5,512,691  | 04/1996                     | Barnicki et al.                       |  |
|  | 9.          | 5,532,002  | 07/1996                     | Story                                 |  |
|  | 10.         | 5,552,167  | 09/1996                     | Taylor et al.                         |  |
|  | 11.         | 5,560,928  | 10/1996                     | Defelice                              |  |
|  | 12.         | 5,591,772  | 01/1997                     | Lane et al.                           |  |
|  | 13.         | 5,645,856  | 07/1997                     | Lacey et al.                          |  |
|  | 14.         | 5,891,469  | 04/1999                     | Amselem                               |  |
|  | 15.         | 5,916,591  | 06/1999                     | Biedel-Willkommen                     | <u> </u>   |
|  | 16.         | 6,008,192  | 12/1999                     | Al-Razzak et al.                      | <u></u>  |
|  | 17.         | 6,056,971  | 05/2000                     | Goldman                               | <u> </u>   |
|  | 18.         | 6,184,255  | 02/2001                     | Mae et al.                            |  |
| 3  | 19.         | 6,365,181  | 04/2002                     | Matthews                              | <u> </u>   |
| August 19 and 19 | 20.         | 6,436,431  | 08/2002                     | Hoffpauer et al.                      |  |
|  | 21.         | 6,623,734  | 09/2003                     | Udell et al.                          |  |
|  | 22.         | 6,664,287  | 12/2003                     | Avery et al.                          | <u> </u>   |
| . A  | 23.         | 6,740,338  | 05/2004                     | Chopra                                |  |
|  | 24.         | 6,782,307  | 08/2004                     | Wilmott et al.                        | <u>and the state of </u> |
| 2 A-1  | 25.         | 6,855,733  | 02/2005                     | Udell et al.                          | <u> </u>   |
|  | 26.         | 6,955,820  | 10/2005                     | Udell                                 |  |
|  | 27.         | 7,015,245  | 03/2006                     | Rich et al.                           | <u></u>  |
|  | 28.         | 7,026,361  | 04/2006                     | Minemura et al.                       |  |
|  | 29.         | 7,060,263  | 06/2006                     | Udeli et al.                          | <u> </u>   |
|  | 30.         | 7,182,950  | 02/2007                     | Garti et al.                          | <u> </u>   |
| and the second s | 31.         | 7,220,429  | 05/2007                     | Udell                                 |  |
|  | 32.         | 7,273,622  | 09/2007                     | Udell et al.                          | <u> </u>   |

| U.S. PUBLICATION DOCUMENTS      |                          |   |                     |  |   |
|---------------------------------|--------------------------|---|---------------------|--|---|
| EXAMINER<br>INITIALS*           | Cite<br>No. <sup>1</sup> | PUBLICATION<br>NUMBER                         | PUBLICATION<br>DATE | Name of Applicant of Cited<br>Document | Pages, Columns, Lines,<br>Where Relevant Passages<br>or Relevant Figures Appear |
|                                 |                          | Number – Kind Code <sup>2</sup><br>(if known) | MM-DD-YYYY          |  | or Relevant Figures Appear  |
|                                 | 33.                      | 2002/0098172                                  | 07/2002             | Udell et al.                           |   |
| Harakan tata dan aya            | 34.                      | 2003/0082168                                  | 05/2003             | Yegorova                               |   |
| April was been been been        | 35.                      | 2003/0119781                                  | 06/2003             | Udell et al.                           |   |
|                                 | 36.                      | 2003/0232076                                  | 12/2003             | Makino et al.                          |   |
| Arabana ana ana ana ana ana ana | 37.                      | 2004/0166157                                  | 08/2004             | Thombre                                |   |
|                                 | 38.                      | 2005/0031681                                  | 02/2005             | Udell et al.                           |   |
|                                 | 39.                      | 2005/0036998                                  | 02/2005             | Udell                                  |   |
|                                 | 40.                      | 2005/0037066                                  | 02/2005             | Udell et al.                           |   |
| Tamasa da ka Sali Lug           | 41.                      | 2005/0069582                                  | 03/2005             | Fantuzzi                               |   |
|                                 | 42.                      | 2005/0169983                                  | 08/2005             | Hassan et al.                          |   |
|                                 | 43.                      | 2006/0013888                                  | 01/2006             | Fantuzzi et al.                        |   |
| in the same start               | 44.                      | 2007/0269508                                  | 11/2007             | Udell                                  |   |
|                                 | 45.                      | 2008/0003279                                  | 01/2008             | Udell                                  |   |
| engen of the control of         | 46.                      | 2008/0020022                                  | 01/2008             | Udell                                  |   |
| kan Magalasah na                | 47.                      | 2008/0089877                                  | 04/2008             | Udell et al.                           |   |
|                                 | 48.                      | 2008/0152707                                  | 06/2008             | Fantuzzi et al.                        |   |
|                                 | 49.                      | 2008/0226710                                  | 09/2008             | Fantuzzi                               |   |

| FOREIGN PATENT DOCUMENTS   |                          |   |                     |   |   |                |
|--|--------------------------|---|---------------------|---|---|----------------|
| EXAMINER INITIALS  | Cite<br>No. <sup>1</sup> | DOCUMENT<br>NUMBER  | PUBLICATION<br>DATE | Name of Patentee or<br>Applicant of Cited | Pages, Columns, Lines,<br>Where Relevant Passages | T <sup>6</sup> |
|  |                          | Country Code <sup>3</sup> –<br>Number <sup>4</sup> – Kind Code <sup>5</sup> (if<br>known) | MM-DD-YYYY          | Document                                  | or Relevant Figures Appear                        |                |
| ilia. A escusión de la companya de l | 50.                      | EP 0 882 450  | 01/1998             | Mae et al.                                |   | 1              |
|  | 51.                      | JP 55081813 *   | 06/1980             | Nisshin Flour Milling                     |   | <b>V</b>       |
|  | 52.                      | JP 59172417 *   | 09/1984             | Nisshin Kagaku KK                         |   | <b>✓</b>       |
|  | 53.                      | WO 00/051574  | 09/2000             | Banner Pharmacaps                         |   | <b>V</b>       |
|  | 54.                      | WO 04/066925  | 08/2004             | R.P. Scherer                              |   | 1              |

|                      | en e | NONPATENT LITERATURE DOCUMENTS  |
|----------------------|--|---|
| EXAMINER<br>INITIALS | Cite<br>No. <sup>1</sup>                 | Include name of Author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. |
|                      | 55.                                      | International Search Report dated February 2, 2005, PCT/US2004/031775 [WO 05/032278], 3 pages   |
|                      | 56.                                      | International Search Report dated May 3, 2005, PCT/US2005/004781 [WO 05/092123], 3 pages  |
|                      | 57.                                      | BHANDARI, et al., "Preparation, Characterization and Evaluation of Coenzyme Q10 Binary Solid Dispersions for Enhanced Solubility and Dissolution," <i>Biol Pharm. Bull.</i> , 2007, Vol. 30, No. 6, pp. 1171-1176   |

|  |                          | NONPATENT LITERATURE DOCUMENTS  |
|--|--------------------------|---|
| EXAMINER<br>INITIALS   | Cite<br>No. <sup>1</sup> | Include name of Author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.   |
|  | 58.                      | BLIZNAKOV, et al., "Biochemical and Clinical Consequencs of Inhibiting Coenzyme Q10 Biosynthesis by Lipid-Lowering HMG-CoA Reductase Inhibitors (Statins): A Critical Overview," <i>Advances in Therapy</i> , July/August 1998, Vol. 15, No. 4, pp. 218-228   |
|  | 59.                      | CHOPRA, et al., "Relative Bioavailability of Coenzyme Q10 Formulations in Human Subjects," <i>Internat. J. Vit. Nutr. Res.,</i> 1998, Vol. 68, pp. 109-113  |
|  | 60.                      | Density of Cooking Oil, <i>The Physics Factbook</i> , edited by Glenn Elert, dated unknown, 3 pages   |
| The Spirit of Spirit Sp | 61.                      | Dictionary.com accessed on 1/17/07, "thixotropic" 1 page  |
|  | 62.                      | Grant & Hackh's Chemical Dictionary, Definition of Gelatin, Fifth Edition, McGraw-Hill Book Company, 1987, p. 258   |
|  | 63.                      | GREENBERG, et al., "Co-enzyme Q10: a new drug for cardiovascular disease," <i>The Journal of Clinical Pharmacology,</i> 1990, Vol. 30, pp. 596-608  |
|  | 64.                      | Merriam-Webster Dictionary OnLine, definition of "elixir," http://www.merriam-<br>webster.com/dictionary/elixir, printed from the June 3, 2009, 2 pages   |
|  | 65.                      | PADILLA-ZAKOUR, "Chemical Food Preservatives: Bonzoate and sorbate," <i>Venture</i> , New York State Agriculture Experimental Station, 1998, Vol. 1, No. 2, 3 pages, found at URL: http://www.nysaes.comeli.edu/necfe/pubs/pdf/Venture/venture2_chemical.html |

|  |          | PROSECUTION DOCUMENTS   |  |  |  |
|--|----------|---|--|--|--|
| EXAMINER Cite No.1   |          | Name of document, date, application number, number of pages   |  |  |  |
|  | 14.41    | USSN 10/792,648 - 7,169,385 (33503/US/2)  |  |  |  |
| a same 24 - Alika Sama   | 66.      | Office Action (Restriction Requirement) dated June 17, 2005, USSN 10/792,648, 10 pages                  |  |  |  |
| and the same   | 67.      | Response to Restriction Requirement dated June 29, 2005, USSN 10/792,648, 8 pages                       |  |  |  |
|  | 68.      | Notice of Allowance and Fee(s) Due and Interview Summary dated July 29, 2005, USSN 10/792,648, 12 pages |  |  |  |
|  | 69.      | Request for Continued Examination dated September 14, 2005, USSN 10/792,648, 2 pages                    |  |  |  |
|  | 70.      | Notice of Allowance and Fee(s) Due dated September 30, 2005, USSN 10/792,648, 5 pages                   |  |  |  |
| and the second case  | 71.      | Request for Continued Examination dated October 14, 2005, USSN 10/792,648, 2 pages                      |  |  |  |
| A San Alleria  | 72.      | Notice of Allowance and Fee(s) Due dated February 15, 2006, USSN 10/792,648, 5 pages                    |  |  |  |
|  |          |   |  |  |  |
| A. M. Lander   | 125 1 44 | USSN 10/953,328 (33503/US/3)  |  |  |  |
| 1000 mil   | 73.      | Restriction Requirement dated October 31, 2005, USSN 10/953,328, 5 pages                                |  |  |  |
|  | 74.      | Response to Restriction Requirement dated November 29, 2005, USSN 10/953,328, 8 pages                   |  |  |  |
|  | 75.      | Office Action dated January 5, 2006, USSN 10/953,328, 18 pages  |  |  |  |
|  | 76.      | Amendment and Response dated April 5, 2006, USSN 10/953,328, 8 pages                                    |  |  |  |
|  | 77.      | Office Action dated April 26, 2006, USSN 10/953,328, 9 pages  |  |  |  |
|  | 78.      | Amendment and Response dated October 26, 2006, USSN 10/953,328, 14 pages                                |  |  |  |
| ning kang langgar di salah sal | 79.      | Office Action (Restriction Requirement) dated November 17, 2006, USSN 10/953,328, 7 pages               |  |  |  |
|  | 80.      | Response to Restriction Requirement dated December 15, 2006, USSN 10/953,328, 9 pages                   |  |  |  |
|  | 81.      | Final Office Action dated January 18, 2007, USSN 10/953,328, 13 pages                                   |  |  |  |

|  |                          | PROSECUTION DOCUMENTS  |
|--|--------------------------|--|
| EXAMINER<br>INITIALS   | Cite<br>No. <sup>1</sup> | Name of document, date, application number, number of pages  |
|  | 82.                      | Request for Continued Examination and Amendment and Response to Final Office Action dated July 12, 2007, USSN 10/953,328, 17 pages |
| ر و روز این  | 83.                      | Final Office Action dated August 7, 2007, USSN 10/953,328, 11 pages  |
|  | 84.                      | Amendment and Response to Final Office Action dated Ocober 5, 2007, USSN 10/953,328, 8 pages                                       |
| <u> </u>   | 85.                      | Declaration Under Rule 1.131 filed October 5, 2007, USSN 10/953,328, 38 pages  |
|  | 86.                      | Request for Continued Examination dated October 29, 2007, USSN 10/953,328, 2 pages   |
| <u> </u>   | 87.                      | Advisory Action dated Novmeber 1, 2007, USSN 10/953,328, 4 pages   |
|  | 88.                      | Office Action dated December 13, 2007, USSN 10/953,328, 8 pages  |
| ائداد أرساسا وكثير   | 89.                      | Declaration Under Rule 1.131 dated February 12, 2008, USSN 10/953,328, 2 pages   |
| n<br>Markaran da markaran da   | 90.                      | Interview Summary dated February 26, 2008, USSN 10/953,328, 2 pages  |
|  | 91.                      | Amendment and Response to Office Action dated April 14, 2008, USSN 10/953,328, 28 pages  |
|  | 92.                      | Final Office Action dated June 3, 2008, USSN 10/953,328, 8 pages   |
| e de la companya de  | 93.                      | Amendment After Final (Under 37 C.F.R. 1.116) dated November 3, 2008, USSN 10/953,328, 19 pages                                    |
|  | 94.                      | Request for Continued Examination dated November 25, 2008, USSN 10/953,328, 2 pages  |
|  | 95.                      | Advisory Action dated December 3, 2008, USSN 10/953,328, 7 pages   |
| Tall to the second seco | 96.                      | Final Office Action dated January 21, 2009, USSN 10/953,328, 9 pages   |
| and the second   | 97.                      | Request for Continued Examination and Amendment and Response to Final Office Action dated May 21, 2009, USSN 10/953,328, 22 pages  |
|  | 98.                      | Supplementary Declaration Pursuant to 37 C.F.R. 1.131 filed May 28, 2009, USSN 10/953,328, 27 pages                                |
| Taking<br>Taking Taking Salah  | 99.                      | Interview Summary dated June 1, 2009, USSN 10/953,328, 3 pages   |
| an Sak mari  | 100.                     | Office Action dated June 22, 2009, USSN 10/953,328, 9 pages  |
|  | . The States             |  |
| i di sasar S   |                          | USSN 11/206,718 - 7,273,606 (33503/US/4)   |
| Tarrella San   | 101.                     | Office Action dated October 23, 2006, USSN 11/206,718, 12 pages  |
|  | 102.                     | Amendment and Response dated April 23, 2007, USSN 11/206,718, 5 pages  |
|  | 103.                     | Terminal Disclaimer dated April 23, 2007, USSN 11/206,718, 2 pages   |
|  | 104.                     | Notice of Allowance and Fee(s) Due dated May 16, 2007, USSN 11/206,718, 7 pages  |
|  |                          | USSN 11/223,718 (33503/US/5)   |
|  | 105.                     | Office Action (Restriction Requirement) dated December 7, 2005, USSN 11/223,718, 5 pages   |
|  | 106.                     | Amendment and Response dated January 6, 2006, USSN 11/223,718, 5 pages   |
|  | 107.                     | Office Action dated March 15, 2006, USSN 11/223,718, 7 pages   |
|  | 108.                     | Amendment and Response dated September 14, 2006, USSN 11/223,718, 18 pages   |
|  | 109.                     | Final Office Action dated October 2, 2006, USSN 11/223,718, 8 pages  |
|  | 110.                     | Notice of Appeal dated April 2, 2007, USSN 11/223,718, 2 pages   |
|  | 111.                     | Request for Continued Examination and Response to Final Office Action dated June 26, 2007, USSN 11/223,718, 21 pages               |
|  | 112.                     | Final Office Action dated July 20, 2007, USSN 11/223,718, 10 pages   |
|  | 113.                     | Request for Continued Examination and Response to Final Office Action dated October 2 2007, USSN 11/223,718, 10 pages              |
|  | 114.                     | Declaration Under Rule 1.131 filed October 2, 2007, USSN 11/223,718, 19 pages  |
|  | 115.                     | Office Action dated October 30, 2007, USSN 11/223,718, 9 pages   |
|  | 116.                     | Response to Office Action dated November 30, 2007, USSN 11/223,718, 19 pages   |
|  |                          |  |
|  | 117.                     | Final Office Action dated January 9, 2008, USSN 11/223,718, 9 pages  |

|  |                          | PROSECUTION DOCUMENTS   |
|--|--------------------------|---|
| EXAMINER<br>INITIALS   | Cite<br>No. <sup>1</sup> | Name of document, date, application number, number of pages   |
| to a constitution and a second   | 119.                     | Interview Summary dated February 25, 2008, USSN 11/223,718, 2 pages   |
|  | 120.                     | Amendment After Final Under 37 C.F.R. 1.116 dated April 9, 2008, USSN 11/223,718, 39 pages  |
|  | 121.                     | Advisory Action dated April 23, 2008, USSN 11/223,718, 5 pages  |
|  | 122.                     | Notice of Appeal dated June 9, 2008, USSN 11/223,718, 2 pages   |
|  | 123.                     | Request for Continued Examination and Amendment After Final Under 37 C.F.R. 1.114 dated October 9, 2008, 24 pages                 |
|  | 124.                     | Final Office Action dated November 17, 2008, USSN 11/223,718, 11 pages  |
| 5 - y 4 June 1 - 1 - 1 - 1 - 1 - 1   | 125.                     | Request for Continued Examination and Amendment and Response to Final Office Action dated May 18, 2009, USSN 11/223,718, 19 pages |
| La Villa Commence  | 126.                     | Supplementary Declaration filed May 18, 2009, USSN 11/223,718, 27 pages   |
|  | 127.                     | Notice of Non-Compliant Amendment dated May 21, 2009, USSN 11/223,718, 2 pages  |
|  | 128.                     | Response to Notice of Non-Compliant Amendment dated June 22, 2009, USSN 11/223,718, 16 pages                                      |
|  | 129.                     | Office Action dated July 24, 2009, USSN 11/223,718, 12 pages  |
| e de la companya del companya de la companya de la companya del companya de la co |                          |   |
| en<br>Deutschaft der eine <u>Jahren</u>  | J                        | USSN 11/860,232 (33503/US/6)  |
| agentago, con el esperante de la companya de la co   | 130.                     | Office Action (Restriction Requirement) dated March 10, 2009, USSN 11/860,232, 6 pages  |
| To the market and the North  | 131.                     | Amendment and Response to Restriction Requirement dated April 10, 2009, USSN 11/860,232, 5 pages                                  |
|  | 132.                     | Interview Summary dated June 4, 2009, USSN 11/860,232, 3 pages  |
|  | 133.                     | Notice of Allowance and Fee(s) Due dated August 7, 2009, 11/860,232, 17 pages   |

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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